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10/763,112	01/21/2004	David Tyvoll	200301164-1	6116

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EXAMINER

HAGEMAN, MARK

ART UNIT	PAPER NUMBER
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3653

DATE MAILED: 08/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/763,112

Applicant(s)

TYVOLL ET AL.

Examiner

Mark Hageman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 29-38 and 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 and 39 is/are rejected.
- 7) ☒ Claim(s) 27 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 January 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1-21-2004.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Invention 1 (Claims 1-28 and 39) in the reply filed on 7-27-2006 is acknowledged.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 186e (page 11 line 29). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The use of the trademark Dupont has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

4. Claim 27 is objected to because of the following informalities: In line 2 the phrase "to so" should read "so". Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. The term "at least substantially" in claim 24 is a relative term which renders the claim indefinite. The term "at least substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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9. Claims 1, 4-9, 11-17, 19, 20, 39 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,808,075 to Bohm et al. Bohm discloses, a channel structure defining a channel having an inlet and first and second outlets (16, 22a, 22b);

a first transport mechanism (12, 12a) configured to create a particle stream of first particles and one or more second particles (C8 lines 61-63), each particle traveling along the channel from the inlet toward the first outlet and disposed in a fluid (C3 lines 30-34) supported by the channel structure; and

a second transport mechanism (100a) configured to be pulse activated to selectively move at least one of the second particles from the particle stream and toward the second outlet (C5 lines 9-12).

-Re claim 4, Bohm discloses, wherein the first transport mechanism is configured to create a flow of the fluid through the channel, and wherein the flow of the fluid creates the particle stream (C3 lines 29-34).

-Re claim 5, Bohm discloses, wherein the first transport mechanism is configured to produce a pressure drop along the channel (C3 lines 29-34).

-Re claim 6, Bohm discloses, wherein the channel structure is configured so that the particle stream follows a path from the inlet to the first outlet without operation of the second transport mechanism (C5 lines 8-9), and wherein the second transport

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mechanism is configured to exert pressure pulses directed transverse to the path (C3 lines 42-43 and figure 100a figure 1).

-Re claim 7, Bohm discloses, wherein one of the pressure pulses is configured to move a fraction of the fluid from the path, the fraction including the at least one second particle (C9 lines 3-5).

-Re claim 8, Bohm discloses, wherein the second transport mechanism includes at least one of a heater element and a piezoelectric element (C11 lines 28-35).

-Re claim 9, Bohm discloses, wherein the channel is a first channel and the inlet is a first inlet (16, 22b), the channel structure defining a second channel (22a) adjacent to the first channel and configured to carry another fluid from a second inlet to a third outlet, and wherein the second outlet (21) of the first channel places the first channel in fluid communication with the second channel (16, 22a, 22b figure 1).

-Re claim 11, Bohm discloses, an optical sensor (C9 26-29) configured to sense the at least one second particle in the particle stream, the optical sensor being coupled to the second transport mechanism so that sensing the at least one second particle actuates the second transport mechanism (C8 lines 63-67).

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-Re claim 12, Bohm discloses, a channel structure defining a channel having an inlet and first and second outlets (16, 22a, 22b figure 1);

a first transport mechanism configured to move first particles and one or more second particles in the channel from the inlet toward the first outlet (12), the first particles and one or more second particles being disposed in a fluid (C3 lines 30-32); and

a second transport mechanism (100a) configured to apply a transient pressure pulse on the fluid so that at least one of the second particles is selectively moved toward the second outlet (C5 lines 7-12).

-Re claim 13, Bohm discloses, wherein the second transport mechanism includes at least one of a heater element and a piezoelectric element (C11 lines 27-35).

-Re claim 14, Bohm discloses, wherein the first transport mechanism is configured to create a flow of the fluid through the channel, and wherein the flow of the fluid carries the first particles and one or more second particles (C3 lines 29-31).

-Re claim 15, Bohm discloses, wherein the second transport mechanism is configured to apply the transient pressure pulse to a segment of the fluid in which the at least one second particle is disposed (C5 lines 10-12).

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-Re claim 16, Bohm discloses, wherein the channel structure is configured so that the first particles and one or more second particles follow a path from the inlet to the first outlet without operation of the second transport mechanism (C5 lines 8-9), and wherein the transient pressure pulse is directed transverse to the path (C3 lines 42-43 and figure 100a figure 1).

-Re claim 17, Bohm discloses, a channel structure defining first and second channels in fluid communication (16, 22a, 22b figure 1);

a first transport mechanism (12, 12a) configured to send respective first and second streams through the first and second channels, the first stream including first particles and one or more second particles (C7 lines 50-56); and

a second transport mechanism (100a) configured to selectively move at least one of the second particles from the first stream to the second stream (C8 lines 65-67 and C9 lines 1-5).

-Re claim 19, Bohm discloses, wherein the first particles and the one or more second particles are different types of cells (C1 lines 23-24).

-Re claim 20, Bohm discloses, wherein the first stream follows a path (16, 22a figure 1), and wherein the second transport mechanism is configured to apply transient pressure pulses to the first stream and transverse to the path (C3 lines 42-43 and figure 1).

-Re claim 39, Bohm discloses, a microfluidic device for sorting particles, comprising:
means for creating a stream of first particles and one or more second particles (12, 12a) disposed in a supported fluid (14); and
means for selectively displacing at least one of the second particles from the stream by exerting a transient force on a portion of the stream (100a figure 1).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 2-3, 18, 21, 22, 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bohm in view of US 6,838,056 to Foster. Bohm discloses all the limitations of the claim except, wherein the channel structure includes a substrate and a plurality of thin-film electrical devices formed on the substrate, and wherein the second transport mechanism is included in the thin-film electrical devices. Foster discloses, wherein the channel structure includes a substrate (c5 lines 16-17) and a plurality of thin-film electrical devices (92) formed on the substrate, and wherein the second transport mechanism is included in the thin-film electrical devices (90, 92), for the

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purpose of creating a separation device that solves throughput, cost and disposability issues (c3 lines 12-15).

It would have been obvious to one of ordinary skill in the art at the time of the applicants' invention to have modified Bohm to include the channel structure including a substrate and a plurality of thin-film electrical devices formed on the substrate, and wherein the second transport mechanism is included in the thin-film electrical devices, as taught by Foster, for the purpose of creating a separation device that solves throughput, cost and disposability issues (c3 lines 12-15).

-Re claim 3, Bohm discloses all the limitations of the claim except, wherein the channel structure includes a fluid barrier connected to the substrate so that the thin-film electrical devices are disposed between the substrate and the fluid barrier. Foster discloses, wherein the channel structure includes a fluid barrier (80) connected to the substrate so that the thin-film electrical devices are disposed between the substrate and the fluid barrier (80, 86, 94) for the purpose of providing a barrier to the fluid mixture and an optically transparent element which allows fluorescent signals to leave (C 4 lines 35-38).

It would have been obvious to one of ordinary skill in the art at the time of the applicants' invention to have modified Bohm to include the channel structure including a fluid barrier connected to the substrate so that the thin-film electrical devices are disposed between the substrate and the fluid barrier, as taught by Foster, for the

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purpose of providing a barrier to the fluid mixture and an optically transparent element which allows fluorescent signals to leave (C 4 lines 35-38).

-Re claim 18, Bohm discloses all the limitation of the claim except, wherein the channel structure includes a substrate and a plurality of thin-film electrical device formed on the substrate. Foster discloses, wherein the channel structure includes a substrate (C5 lines 16-17) and a plurality of thin-film electrical devices formed on the substrate (92), for the purpose of creating a separation device that solves throughput, cost and disposability issues (c3 lines 12-15).

It would have been obvious to one of ordinary skill in the art at the time of the applicants' invention to have modified Bohm to include wherein the channel structure includes a substrate (C5 lines 16-17) and a plurality of thin-film electrical devices formed on the substrate (92), as taught by Foster, for the purpose of creating a separation device that solves throughput, cost and disposability issues (c3 lines 12-15).

-Re claim 21, Bohm discloses all the limitations of the claim except, a substrate assembly including a substrate and a fluid barrier connected to the substrate, the substrate assembly defining a channel having an inlet and first and second outlets; and a thin-film electrical device formed on the substrate and configured to be pulse-activated to selectively move at least one of the second particles from the particle stream and toward the second outlet. Foster discloses, a substrate assembly including a substrate (94) and a fluid barrier (80) connected to the substrate, the substrate

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assembly defining a channel having an inlet (96) and first and second outlets (104, 106); and a thin-film electrical device (92) formed on the substrate and configured to be pulse-activated to selectively move at least one of the second particles from the particle stream and toward the second outlet (C5 lines 2-10), for the purpose of the purpose of creating a separation device that solves throughput, cost and disposability issues (C3 lines 12-15).

It would have been obvious to one of ordinary skill in the art at the time of the applicants' invention to have modified Bohm to include a substrate assembly including a substrate and a fluid barrier connected to the substrate, the substrate assembly defining a channel having an inlet and first and second outlets; and a thin-film electrical device formed on the substrate and configured to be pulse-activated to selectively move at least one of the second particles from the particle stream and toward the second outlet, as taught by Foster, for the purpose of the purpose of creating a separation device that solves throughput, cost and disposability issues (C3 lines 12-15).

-Re claim 22, Bohm further discloses, wherein the transport mechanism (12, 12a 14) is configured to apply at least one of a positive and a negative pressure to a fluid in which the first particles and one or more second particles are disposed.

-Re claim 24 Foster further discloses, wherein the substrate is formed at least substantially of silicon or glass (94 figure 1) for the purpose of patterning the MEMS devices by lithographic means (C5 lines 16-17).

It would have been obvious to one of ordinary skill in the art at the time of the applicants' invention to have modified Bohm to include wherein the substrate is formed at least substantially of silicon or glass, as taught by Foster, for the purpose of patterning the MEMS devices by lithographic means (C5 lines 16-17).

-Re claim 25, Bohm discloses, wherein the thin-film electrical device is one of a heater element and a piezoelectric element (C11 lines 29-36).

-Re claim 26, Foster further discloses, an optical sensor disposed adjacent or in the substrate and configured to sense a position of one or more second particles within the channel (C3 lines 62-63) for the purpose of controlling the actuator which separates the samples (C3 lines 61-62).

It would have been obvious to one of ordinary skill in the art at the time of the applicants' invention to have modified Bohm to include an optical sensor disposed adjacent or in the substrate and configured to sense a position of one or more second particles within the channel, as taught by Foster, for the purpose of controlling the actuator which separates the samples (C3 lines 61-62).

-Re claim 27, Foster further discloses, wherein the optical sensor is configured so that an actuation signal for the thin-film electrical device is produced based on the position (C5 lines 34-36) for the purpose of allowing only the fluorescing cell to be sorted

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and to minimize the chance of errant non-flourescing cells be sorted mistakenly (C5 lines 22-25).

It would have been obvious to one of ordinary skill in the art at the time of the applicants' invention to have modified Bohm to include wherein the optical sensor is configured so that an actuation signal for the thin-film electrical device is produced based on the position, as taught by Foster, for the purpose of allowing only the flourescing cell to sorted and to minimize the chance of errant non-flourescing cells be sorted mistakenly (C5 lines 22-25).

-Re claim 28, Bohm discloses, wherein the first particles and the one or more second particles are different types of cells (C1 lines 23-24).

12. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bohm in view of US 4,216,477 to Matsuda et al. Bohm discloses, the channel structure defines a passage disposed in fluid communication with the channel and generally opposing the second outlet (figure 1). Bohm does not disclose, wherein the passage includes a fluid diode configured to restrict fluid backflow created by operation of the second transport mechanism. Matsuda discloses, the passage includes a fluid diode (10) configured to restrict fluid backflow created by operation of the second transport mechanism, for the purpose of providing a great impedance ratio for the transient flow of liquid (C5 lines 21-22).

It would have been obvious to one of ordinary skill in the art at the time of the applicants' invention to have modified Bohm to include wherein the passage includes a fluid diode configured to restrict fluid backflow created by operation of the second transport mechanism, as taught by Matsuda, for the purpose of providing a great impedance ratio for the transient flow of liquid (C5 lines 21-22).

13. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bohm in view of Foster as applied to claims 2-3, 18, 21, 22, 24-28 above, and further in view of "An integrated Microfabricated Cell Sort" by Fu et al. Bohm in view of Foster discloses all the limitations of the claim except, wherein the transport mechanism operates to create the particle stream by dielectrophoresis. Fu et al disclose, wherein the transport mechanism operates to create the particle stream by dielectrophoresis (para 1 lines 13-14) for the purpose of creating valveless switches for separation of particles and cells within microchannels (para 1 line 14-15).

It would have been obvious to one of ordinary skill in the art at the time of the applicants' invention to have modified Bohm in view of Foster to include wherein the transport mechanism operates to create the particle stream by dielectrophoresis, as taught by Fu, for the purpose of creating valveless switches for separation of particles and cells within microchannels (para 1 line 14-15).

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Hageman whose telephone number is (571) 272-3027. The examiner can normally be reached on M-F 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Mackey can be reached on (571) 272-6916. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MCH



**PATRICK MACKEY
PRIMARY EXAMINER**